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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,396	08/06/2001	Wolff M. Kirsch	LOMAU.140A	6247
5318	7590	01/03/2005	EXAMINER	
NATIONAL INSTITUTES OF HEALTH OFFICE OF TECHNOLOGY TRANSFER 6011 EXECUTIVE BLVD SUITE 325 ROCKVILLE, MD 20852-3804			CHERNYSHEV, OLGA N	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 01/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/924,396

**Applicant(s)**

KIRSCH ET AL.

**Examiner**

Olga N. Chernyshev

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-9 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-9 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                         |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____                                                             | 6) <input type="checkbox"/> Other: _____                                    |

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***Response to Amendment***

1. Claims 7 and 21 have been amended as requested in the amendment filed on October 25, 2004. Claims 7-9 and 21 are pending in the instant application.

Claims 7-9 and 21 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on October 25, 2004 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

***Claim Objections***

5. Claim 21 stands objected for reasons of record in section 6 of Paper mailed on April 21, 2004. Appropriate correction or clarification is required.

***Claim Rejections - 35 USC § 112***

6. Claims 7-9 and 21 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record in section 7 of Paper mailed on April 21, 2004.

Applicant traverses the rejection on the premises that the instant specification, as filed, fully satisfies the requirements of enablement, as set in *In re Wands* (middle at page 4 of the

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Response). Applicant submits that only a minimal experimentation would be necessary to carry out the assays because ELISA, western blot or FACS analysis are all very sensitive assays (see also reasoning in section (5) to (7) on page 5 of the Response). However, it appears that Applicant mischaracterizes the issue of “undue experimentation”. One skilled in the art readily appreciates that type of assay and the sensitivity of an assay would influence “the difference between the control and sample” (bottom at page 4). There is also no disagreement that the skill in the art is high and routine, even complex, assays could be performed by a skilled practitioner. Nevertheless, because the instant specification, as originally filed, does not disclose any specific quantitative data regarding the levels of IRP-2 predictive of Alzheimer’s disease or MCI or particular mutations in IRP-2 gene as markers for Alzheimer’s disease or MCI, a skilled practitioner would have to perform a significant amount of further research to discover how to identify a subject with Alzheimer’s disease (AD) or MCI or a defect in iron metabolism by practicing the steps of the claimed methods.

Applicant further submits statements that “the amount of direction and/or guidance presented is sufficient” and that it is not necessary to provide working examples to satisfy the enablement requirement (sections (2) and (3) at page 5 of the Response). The Examiner maintains the position that, as fully explained in the previous communication of record, in view of the unpredictability of the art related to diagnosis of Alzheimer’s disease, lack of guidance regarding clear protocol on how to practice the claimed method or any reference to examples, prophetic or actual on how similar methods were practiced, the instant specification is not found to be enabling for a method of identifying a subject as likely to develop or have AD or MCI or to

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identify a defect in iron metabolism by comparing amounts of probe that interacts with IRP-2 in a sample of peripheral blood cells.

Applicant's arguments in Section (4) are not clear and, therefore, are not answered.

With regard to claim 21, it appears that Applicant argues issues of enablement and utility concurrently (Applicant submits that "[t]o be useful as a diagnostic, the identification of a higher than normal amount of IRP-2 is used in addition to other factors to identify its usefulness" (top at page 6 of the Response). Applicant is advised that claim 21 is rejected due to the lack of enablement under 35 U.S.C. 112, first paragraph for those reasons of record as fully explained on page 6 of the office action mailed on April 24, 2004.

***Claim Rejections - 35 USC § 112***

7. Claims 7-9 and 21 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record in section 9 of the Paper mailed on April 24, 2004. Specifically, claims 7 and 21 stand vague and indefinite in so far as they employ the term "mutant IRP-2" as a limitation. Applicant argues that "one skilled in the art with the teaching in the specification could determine what a mutant IRP-2 protein is". This is not considered to be persuasive because if the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "mutant IRP-2", an artisan clearly cannot determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation. Claims 8-9 are indefinite for being dependent from indefinite claim.

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***Conclusion***

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax

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center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Olga N. Chernyshev, Ph.D.  
Primary Examiner  
Art Unit 1646

December 27, 2004